Results of transvenous lead extraction of coronary sinus leads in patients with cardiac 4,703 resynchronization therapy

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Abstract: BACKGROUND: The need for transvenous lead extraction procedures of coronary sinus (CS) leads is increasing due to rising numbers of implanted cardiac resynchronization therapy devices during the past decade. METHODS: From January 2009 to June 2013, 27 CS leads were scheduled for extraction in 27 patients (mean age (63.1±14.6) years). Indications for lead extraction were infection in 13 and lead dysfunction in 14 cases. Isolated extraction of CS leads was performed in eight, extraction of multiple leads in 19 cases. Among leads with an implant time of 12 months (n = 19) mean implant duration (MID) was (46.4±15.2) (12-76) months. Groups were formed depending on infectious or non-infectious indications (INF vs. Non-INF), and the use or non-use of extraction tools (ET1 vs. ET0). RESULTS: Among patients with an implant duration of 12 months, complete procedural success was 94.7% and clinical success 100%. Operative mortality was zero. In the INF versus NON-INF groups complete procedural success (100% vs. 91.7%, P = 0.43), mean number of required extraction tools (0.7 (0-2) vs. 0.9 (0-3), P = 0.65) and MID (49.1±15.0 vs. 44.7±15.8, P = 0.83) did not differ significantly. Comparing the groups ET1 and ET0 showed no significant differences in complications (n = 1 vs. n = 1, P = 0.81) and MID (47.0±17.5 vs. 45.5±12.6, P = 0.71). CONCLUSIONS: In specialized centers transvenous lead extraction of coronary sinus leads with a mean implant duration of almost four years can be performed safely and effectively. Neither non-infectious indications nor the use of extraction tools negatively affected the outcome of the procedure.

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Original article

Results of transvenous lead extraction of coronary sinus leads in patients with cardiac resynchronization therapy

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Keywords: *lead extraction; coronary sinus leads; pacemaker; implantable cardioverter defibrillator; cardiac resynchronization therapy*

Background The need for transvenous lead extraction procedures of coronary sinus (CS) leads is increasing due to rising numbers of implanted cardiac resynchronization therapy devices during the past decade.

Methods From January 2009 to June 2013, 27 CS leads were scheduled for extraction in 27 patients (mean age (63.1±14.6) years). Indications for lead extraction were infection in 13 and lead dysfunction in 14 cases. Isolated extraction of CS leads was performed in eight, extraction of multiple leads in 19 cases. Among leads with an implant time of ≥12 months (*n*=19) mean implant duration (MID) was (46.4±15.2) (12–76) months. Groups were formed depending on infectious or non-infectious indications (INF vs. Non-INF), and the use or non-use of extraction tools (ET1 vs. ET0).

Results Among patients with an implant duration of ≥12 months, complete procedural success was 94.7% and clinical success 100%. Operative mortality was zero. In the INF versus NON-INF groups complete procedural success (100% vs. 91.7%, *P*=0.43), mean number of required extraction tools (0.7 (0–2) vs. 0.9 (0–3), *P*=0.65) and MID (49.1±15.0 vs. 44.7±15.8, *P*=0.83) did not differ significantly. Comparing the groups ET1 and ET0 showed no significant differences in complications (*n*=1 vs. *n*=1, *P*=0.81) and MID (47.0±17.5 vs. 45.5±12.6, *P*=0.71).

Conclusions In specialized centers transvenous lead extraction of coronary sinus leads with a mean implant duration of almost four years can be performed safely and effectively. Neither non-infectious indications nor the use of extraction tools negatively affected the outcome of the procedure.

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The number of implanted cardiac resynchronization therapy (CRT) devices has increased enormously during the last decade. At present approximately 100 000 CRT devices are implanted yearly in Europe with regional differences.[1] Given the need for lead extractions, which was estimated as 1.5%–6% in the position paper of the European Heart Rhythm Association (EHRA), this would mean 1500–6000 extractions of coronary sinus (CS) leads per year in Europe.[2] In general, transvenous lead extraction procedures can currently be carried out with high success rates and low complication rates.[3-7] Most reported experiences with extraction procedures refer to the removal of right atrial or right ventricular leads with few studies investigating the extraction of CS leads. In this retrospective study we analyzed our extraction experience of CS leads with regard to indications, extraction tools, success, and complication rates.

METHODS

Patient population

All transvenous lead extraction procedures performed between January 2009 and June 2013 were screened. In this time interval 152 patients underwent lead extraction procedures with 259 leads scheduled for extraction. Patients were included if coronary sinus lead extraction was performed. Twenty-seven patients (18 male, 9 female) with 27 coronary sinus leads scheduled for extraction were identified. Mean age was (63.1±14.6) years, range 29–90 years.

All CS leads were passive fixation leads. Indication for extraction was infection in 13 cases and non-functional leads in 14 cases. Isolated extraction of CS leads was performed in eight cases, extraction of multiple leads in 19 cases. For statistical analysis, leads with an implant time of 12 months and more were selected (*n*=19). Among these leads the mean implant time was (46.4±15.2) months, range 12–76 months. Groups were formed based on infectious (*n*=7) or non-infectious (*n*=12) indication and the necessity to use extraction tools (*n*=11) or extraction without tools (*n*=8).The preoperative patient and lead data are displayed in Table 1.

Appropriate institutional review board approval was obtained. The results of the different groups were analyzed and compared.

Extraction procedure

If leads could not be extracted by simple traction, a staged

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Table 1. Preoperative patient and lead data

Characteristics	Preoperative value
Patients (*n*)	27
Gender (*n*)	
Male	18
Female	9
Mean patient age (years)	63.1 (29–90)
Leads overall (*n*)	27
Leads ≥12 months ID (*n*)	19
MID all leads (months)	33.3 (1–76)
MID leads ≥12 months ID (months)	46.4 (12–76)
Indication for lead extraction (*n*)	
Infection	13
Dysfunctional lead	14
Isolated vs. multiple lead extractions (*n*)	
Isolated CS lead extraction	8
Multiple lead extraction	19
Underlying disease (*n*)	
Dilated cardiomyopathy	21
Ischemic cardiomyopathy	6
Ejection fraction prior to lead extraction procedure (%)	37.1±13.3
Left ventricular end-diastolic diameter prior to lead extraction procedure (mm)	62.8±12.0

approach was performed. Access to the lead scheduled for extraction was obtained by a superior, subclavian approach. After freeing the lead of the fibrotic adhesions in the generator pocket, the fixation sutures of the lead were removed. For application of traction, as a first step, a locking stylet was used (Liberator, Cook Medical, USA or Lead Lock Device, Spectranetics, USA). In cases where traction with the locking stylet was not sufficient, counterpressure or countertraction using powered or non-powered extraction sheaths was added. To apply counterpressure or countertraction, polypropylene extraction sheaths (Byrd Dilator Sheath, Cook Medical, USA) were first used in a telescoping sheath technique. If not successful a further step with a mechanical dilator sheath (Evolution, Cook Medical, USA) or a laser sheath (SLS II, Spectranetics, USA) was performed. Beginning in December 2010 the mechanical dilator sheath was primarily applied, before that date the laser sheath was used regularly. In case of failed or impossible subclavian approach, a femoral snare extraction technique was performed using the Needle's Eye Snare device (Cook Medical, USA) via the right femoral vein (Figure 1). Lead extraction procedures were performed in an operation theater with general anesthesia by a cardiac surgeon with standby of extracorporeal circulation. Patients were continuously monitored by electrocardiogram (ECG), invasive blood pressure measurement, pulse oximetry, and transesophageal echocardiography. Success was defined either as complete procedural success or as clinical success according to the definitions of the expert consensus on transvenous lead extraction by the Heart Rhythm Society.[8]

Statistical analysis

Data were analyzed using the SPSS software Version 20.0 (IBM Corporation, USA). Categorical variables are presented as numbers and percentages. Differences between groups were analyzed using the Chi square test. Continuous variables are presented as mean ± standard deviation or as mean and range from minimum to maximum. Mann-Whitney *U* test for independent samples was performed to analyze the differences between groups. A *P*-value of less than 0.05 was considered significant.

RESULTS

Among leads with an implant duration of at least 12 months the complete procedural success rate was 94.7% and clinical success 100%. Operative mortality was zero. One major complication occurred in a multiple lead extraction procedure, which was not related to the extraction of the coronary sinus lead. The patient suffered from a right ventricular tear after extraction of a right ventricular ICD lead and required an emergency thoracotomy. The patient survived. One pocket hematoma requiring surgical drainage was noted as a minor complication. No coronary sinus complications were seen.

Infectious versus non-infectious indications

When analyzing the results with regard to infectious (INF) or non-infectious (NON-INF) indications, it was noted that mean implant duration was not significantly different in the two groups; INF vs. NON-INF: (49.1±15.0) months vs. (44.7±15.8) months (*P*=0.83). The rates of complete procedural success showed no significant difference between the two groups (*P*=0.43) being 100% in the INF group and 91.7% in the NON-INF group. The mean number of required extraction tools was 0.7 (0–2) tools in the group INF and 0.9 (0–3) tools in the NON-INF group; with no statistically significant difference (*P*=0.65) (Table 2). In the INF group no immediate re-implantation of coronary sinus

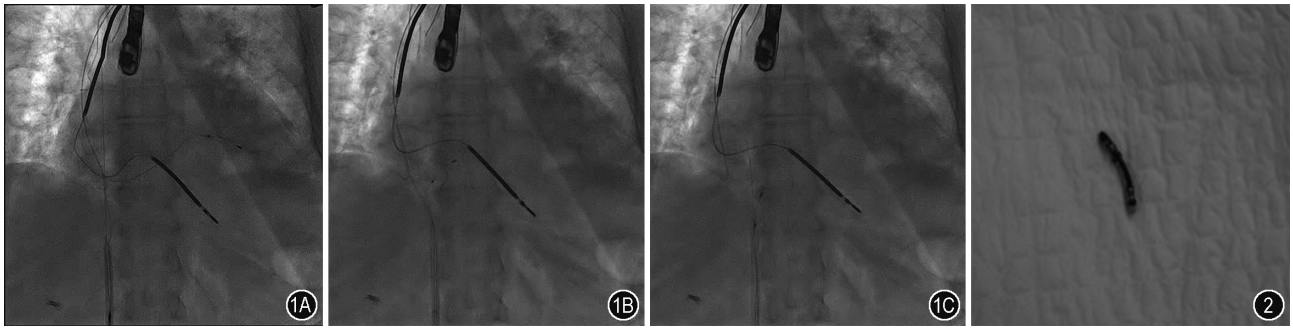

Figure 1. Extraction of a coronary sinus lead using a femoral snare device (Needle's Eye Snare, Cook Medical).
Figure 2. Due to their design with mostly smaller diameters of the lead body compared to right atrial and right ventricular leads, coronary sinus leads are physically less resistant to extraction forces and therefore have a higher risk for lead rupture during the extraction procedure.

leads was performed. Among the patients of the NON-INF group (n=12) a re-implantation of a coronary sinus lead was attempted in seven cases with success in all cases. In three patients an epicardial left ventricular lead was directly implanted without attempting transvenous implantation.

Use of extraction tools

With regard to the use of extraction tools, mean implant duration did not show significant differences between the two extraction tools groups; ET1 (47.0±17.5) months vs. ET0 (45.5±12.6) months (P=0.71). Also the number of complications was low and revealed no differences; ET1 n=1 vs. ET0 n=1 (P=0.81) (Table 3). The distribution of the number of extraction tools used with the corresponding number and percentage of leads, as well as the corresponding mean implant duration, is displayed in Table 4.

DISCUSSION

There are several special aspects to lead extractions of CS leads which may lead to an increased difficulty of such procedures. The design of CS leads is different from right atrial and right ventricular leads with smaller diameters of the lead body in most cases and, therefore, less physical resistance to extraction forces and a higher risk for lead rupture (Figure 2). In order to avoid lead damage the application of counterpressure or countertraction for CS lead extraction has to be performed more carefully in comparison to extraction of right atrial or right ventricular leads. Lead-lead-interactions may also be encountered during extraction procedures of CS leads, which can necessitate the extraction of other leads not scheduled for removal. Furthermore, venous stenosis or occlusion may be encountered more frequently due to the higher number of implanted leads.[9,10]

Due to the large numbers of implanted cardiac resynchronization therapy devices in heart failure patients, an increasing number of coronary sinus lead extractions may be expected in the coming decade.[1,2] There are many studies investigating the extraction of right atrial or right ventricular leads, however investigations of transvenous extraction procedures of coronary sinus leads have been published less frequently.[6,7,11-14] Most studies addressing coronary sinus lead extraction have investigated leads with a mean implant duration of 30 months or less.[13-17] In our study, mean implant duration of the leads was 46 months, ranging from 12 to 76 months. Even though the mean implant duration was longer than in the studies mentioned above, our rates of complete procedural success and clinical success compare favorably with the success rates in the published data. This fact should not lead to the assumption that the success of extraction procedures of transvenous left ventricular leads will stay high despite increasing implant durations, since it was shown in other lead extraction studies that success rates begin to decrease significantly with implant duration of ten years and more.[5,7,12,18] With the results from other investigations in mind, we might still be facing a challenging extraction procedures of coronary sinus lead procedures in the future. In contrast, transvenous extraction of active fixation coronary sinus leads (Medtronic Starfix®) are known to be more challenging even in cases with short duration implants.[16,17]

When analyzing the data of infectious or non-infectious indications for lead extraction, we were able to show that the difficulty (expressed by the mean number of extraction tools) and success of the operation did not differ significantly, and the mean implant duration was similar in both groups. This is in contrast to the data of Byrd et al[18] on lead extractions of right atrial and right ventricular leads. They reported that the risk of incomplete or failed extraction increased with non-infected patients, among other factors. It is important, however, to mention that the data in Byrd's study are from almost twenty years ago. Currently, several improved high-end extraction tools have been introduced for clinical application, which has certainly improved success rates, even in difficult cases with extensive lead fibrosis.[7,19,20]

Lead extraction is known to be a safe procedure with current techniques.[6,11,21] Despite this fact, in a small percentage of cases, major, and possibly life-threatening, complications can occur during such operations, possibly related to the use of extraction tools.[22] In extraction of transvenous left ventricular leads this may be relevant due to the anatomical position of the lead. The coronary venous system is more fragile than myocardial tissue of the right ventricle or the right atrium. Therefore we analyzed our results with regard to the use or the non-use of extraction

Table 2. Results of extraction procedures of leads with ≥12 months implant duration with regard to indication

Characteristics	INF (7 leads)	Non-INF (12 leads)	P values
Patient age (years)	67.2±6.5	60.3±16.4	0.48
Gender (%)			
Male	57.1	75.0	0.41
Female	42.9	25.0	
Mean implant duration (months)	49.1±15.0	44.7±15.8	0.83
Complete procedural success (n (%))	7 (100.0)	11 (91.7)	0.43
Mean number of required extraction tools	0.7 (0–2)	0.9 (0–3)	0.65

INF: infectious indication; NON-INF: non-infectious indication.

Table 3. Results of extraction procedures of leads with ≥12 months implant duration with regard to the use of extraction tools

Characteristics	ET1 (11 leads)	ET0 (8 leads)	P values
Patient age (years)	61.2±14.3	65.3±13.7	0.60
Gender (%)			
Male	54.5	87.5	0.12
Female	45.5	12.5	
Mean implant duration (months)	47.0±17.5	45.5±12.6	0.71
Complications (n)	1	1	0.81

ET1: use of extraction tools; ET0: extraction without tools.

Table 4. Distribution of the number of extraction tools used with regard to mean implant duration in leads with ≥12 months implant duration

Characteristics	Number of extraction tools used			
	0	1	2	3
Number of leads (n (%))	8 (42.1)	7 (36.8)	3 (15.8)	1 (5.3)
Mean implant duration (months)	45.5±12.6	42.9±17.5	54.3±21.0	54.0±0

tools. Implant duration did not differ significantly between these two groups and complication rates were low in both groups without differences. Complications related to the coronary venous system were not seen. Of course, the results of complications need to be interpreted very carefully since the numbers are small. In addition, reported general rates of major complications mostly vary between 0% and 4%, which from a statistical standpoint necessitates large patient populations to draw solid conclusions from comparisons of different groups.[4,6]

Limitations of this study are its retrospective design, the fact that it is a single-center experience and the small size of the patient population. Studies with larger patient populations should be performed in the future. In specialized centers transvenous lead extraction of coronary sinus leads with a mean implant duration of almost four years can be performed safely and effectively. Neither non-infectious indications nor the use of extraction tools negatively affected the outcome of the procedure. But with increasing implant duration, extraction of coronary sinus leads might become more challenging in the future.

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